

## REMARKS

By this amendment, Applicants have amended the wording of Claims 5, 23 and 24, and have amended Claim 17 by placing the subject matter relating to the oral administration of two to four times daily in new dependent claim 25. Applicants submit that these amendments are fully supported in the specification (see, e.g., p.6, lines 15-25; p.7, lines 31-32; p.8, lines 7-8 and Example, p.13, lines 23-24), and no new matter has been added. Applicants submit that the present application has been placed in condition for allowance for the reasons as set forth below.

In the Official Action, the Examiner objected to the Abstract. However, since this is a National Stage filing, the Abstract is proper. In a National Stage application, “The requirement of 37 CFR 1.52(b) that the abstract ‘commence on a separate physical sheet or electronic page’ **does not apply** to the copy of the published international application communicated to the designated Offices by the International Bureau under PCT Article 20.” See MPEP 1893.03(e).

In the Official Action, the Examiner objected to Claim 23 as being a substantial duplicate of Claim 5 and to Claim 24 as being a substantial duplicate of Claim 20. This objection is traversed by virtue of the present amendments.. Similarly, the Examiner objected to Claims 5-19 and 24 as failing to limit the subject matter of a previous claim, and because of the open claim language, and these objections have also been traversed by the present amendments.

In the Official Action, the Examiner objected to the use of the language “consisting essentially of” in the claims under 35 U.S.C. §112, first paragraph, on the alleged basis that Applicant did not include the language “consisting essentially of” in the original specification. This rejection is respectfully traversed in that the specification never needs to include *ipsis verbis* (i.e., word for word) support for claim language, even for negative limitations, e.g., those limitations defining the scope of the claims. *See, e.g., In re Wertheim*, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976), *Martin v. Johnson*, 454 F.2d 746, 751, 172 USPQ 391, 395 (CCPA 1972) (stating “the description need not be in *ipsis verbis* [i.e., “in the same words”] to be sufficient”). Applicants’ specification clearly sets forth the parameters of the claimed invention such that one skilled in the art would clearly understand that the form of the invention using the accepted transactional phrase “consisting essentially of” was described so as to convey that Applicants had possession of the claimed invention at the time of filing.

In the Official Action, the Examiner rejected Claims 1 and 5-24 under 35 U.S.C. §103(a) as obvious over the Cojocarú et al. article in view of the Cubeddu and Boige articles. This rejection is respectfully traversed for the reasons as stated below.

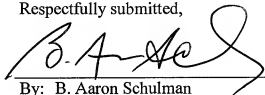
Contrary to the Examiner’s assertions, Cojocarú et al. merely discloses the benefits of racecadotril administration for acute diarrhea treatment rehydration, lower number of stools and faster recovery. This reference does not mention or suggest the combination of racecadotril with any antiemetic agent, and is silent about ondansetron or granisetron. Applicants respectfully submit that this document does not teach any information beyond what the skilled artisan would already know.

Moreover, the cited Cubeddu et al. reference merely discloses the antiemetic activity of ondansetron in acute gastroenteritis and is totally silent about a combination of ondansetron with racecadotril. Finally, Boige et al. merely suggests how to achieve an antidiarrheic activity and an antiemetic activity in patients in need thereof, but does not teach or suggest administration of racecadotril with ondansetron for achieving the inhibition of side effects of racecadotril, and the potentialization of the antidiarrheic effect of racecadotril. Accordingly, neither Cubeddu nor Boige make up for the deficiencies in the Cojocar article, and do not make the present claims obvious.

Applicants thus respectfully submit that the present claims are not obvious in light of the prior art, either singly or in combination, and that the Examiner's rejection on this basis is respectfully traversed and should be withdrawn.

In light of the amendments and arguments provided herewith, Applicants submit that the present application overcomes all prior rejections and objections, and, upon entrance of the present amendments, will be placed in condition for immediate allowance. Such action is respectfully requested.

Respectfully submitted,



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